REMARKS

Claims 1-4, 21, 23, 24, 26 and 27 are currently pending. Claims 1-4, 5-12, 13-21, and 23- 25 are amended and are also under consideration. New claims 26 and 27 are added.

The Examiner has rejected claims 1-4, 21, 23 and 24 based on prior art cited in the February 5, 2003 Office Action. The Examiner states in her September 17, 2003 Office Action that *"The pages and line numbers pointed to fail to provide support for the limitations made in the amendment dated May 22, 2003."*

<u>Office Action of February 5, 2003</u>

Claims 1-4 and 21-24 were rejected under 35 U.S.C. 102(e) as being anticipated by Armstrong et al., U.S. 6,099,469). The Action states:

"As stated previously, Armstrong et al, meet the limitations of the steps set forth in the generic claims and the apparatus of Armstrong et al meets all of the limitations of the generic apparatus of the instant invention.

As set forth, Armstrong et al disclose a disease specific algorithm for use in a computer assisted method that analyzes what clinical tests should be performed. The particular disease state of Armstrong et al is acute myocardial infarction. A first test is performed on the sample, then, based upon result comparisons with preset guidelines, a second test is run. In the conditions set forth in column 3, line 52- column 4, line 12, it is clear that the invention of

Armstrong provides means for omitting the execution of unnecessary assays while ensuring that all necessary combinations of laboratory tests are covered. Furthermore, the reflex algorithm of the invention automatically selects appropriate markers for a given clinical situation such that human decision-making is eliminated.

In Response, applicant applicant has amended claim 1 as advised during the interview. Armstrong et al.'s reflex algorithm is used to monitor a number of biochemical markers, which change in a time-sensitive manner during a myocardial infarction episode, for example creatinine kinase, myoglobin and troponin. These time dependent changes in the specific biomarkers are monitored by a technician in order to determine the stage at which the myocardial infarction is being monitored. And, sometimes, this requires that the same biomarker test be run repeatedly every four hours in order to follow the progression of the myocardial infarct. In other words, it is the technician who decides as to whether to repeat any testing. The reflex algorithm merely indicates how a measurement for a biomarker compares with a predetermined level.

In contrast, in the present invention, the entire algorithm is computer controlled. The first step in the algorithmic clinical testing is for the computer to determine which of the tests ordered by a physician are truly essential to diagnose a specific suspected disease. After this, the algorithm executes the necessary tests in a sequential manner, to obtain an accurate diagnosis. The present system is run by the computer using the decision-support software. See

page 2, line 15. It does not require a technician or operator to run the test. The objective in the present invention is to provide a cost-effective, rapid, efficient system that can be used in the diagnosis of many diseases in which the markers being measured have stable values. See specification page 2, line 15 to page 3 line 9 of the specification. The system is capable of carrying out intelligent programming to effectuate diagnosis and does not need the technician to make the decisions as is the case in Armstrong et al. The section cited in the rejection does not cover the above distinguishing element, and therefore, as a matter of fact and law, the above rejection must be withdrawn. This is because the Federal Circuit has held that:

"It is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention". _Hybritech Inc. v. Monoclonal Antibodies Inc._ 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986). "For a prior art reference to anticipate in terms of 35 U.S.C.Section 102, every element of the claimed invention must be identically shown in a single reference ... These elements must be arranged as in the claim under review, ..." _In re Bond,_ 910 F.2d 831, 15 USPQ 1566 (Fed. Cir. 1990)."

Therefore, as a matter of law and fact, the rejection of claims 1-4 and 21-24 based on Armstrong et al. must be withdrawn.

Claims 1-4 and 21-24 were rejected under 35 U.S.C. 102(e) as being anticipated by Carlson et al. (U.S. 6,140,065). The Action States:

Carlson et al (US 6,140,065) disclose computer-assisted methods for

diagnosing a disease state based upon a reflex algorithm. Applicant argues that

the amendments to the claims make them allowable over Carlson. However, as

stated above in reference to Armstrong et al, the claims state that tests are run

on a sub-group showing abnormality, thereby not allowing unnecessary clinical

tests to be carried out in duplicate or to be ordered by an outside operator.

However, this does not imply that the tests still cannot be run or that an operator

is not utilized when a necessary test is indicated. The rejection is maintained.

In response, applicant has amended claim 1 as advised. Importantly,

Carlson does not have the essential element of the algorithm – the whole test is

run by the computer. See page 2, line 15 to page 3, line 9 of the specification.

Carlson requires that an operator enter the age of the patient during the course

of the testing. The present algorithm also incudes a bone measurement which is

not a test in Carlson's algorithm.

The legal standard for a section 102 rejection, requiring each and every

element to be present in the cited reference, as discussed above, applies to this

rejection as well. Therefore the rejection based on Carlson must be withdrawn

as a matter of law and fact.

Claims 1-4, 18 and 21-24 were rejected under 35 U.S.C. 102(b) as being

anticipated by Adlassnig et al. (Artificial Intelligence in Medicine, (1995) Vol 7.

pages 1-24). The Action states:

Adlassing et al disclose the HEPAEXPERT –1 computer algorithm that is

useful in obtaining a diagnosis of HBV infection. As shown in figure 2 and 3

typical serology for a variety of HBV infection are used for identifying which

clinical tests to run. Rules are written in to computer memory for normal and typical scenarios of HBV infection and the computer goes through a variety of test combinations to establish a diagnosis. The programmed computers of Adlassnig et al meet all of the limitations of the instant claims.

In response, applicant has amended claim 1 as advised. Adlassnig does not meet the following limitation of the instant claims: the present algorithm is fully run by the computer and does not require an operator, and the algorithm selects at the first stage, only tests relevant to the diagnosis of a specific suspected disease, irrespective of the tests ordered by a physician. See page 2, line 15 to page 3 line 9 of the specification.
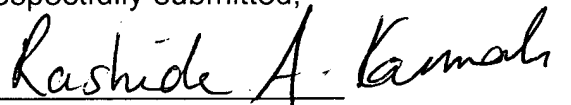
This limitation has important implications in making the health system cost effective. This is because physicians usually order unnecessary tests, sometimes unrelated to the diagnosis of a suspected disease, usually under the guise of "routine health check-up". The algorithms developed in present invention prevent the unnecessary tests and stop an operator from overriding the algorithm.

As discussed by applicant's attorney during the interview on March 30, 2004, none of the cited references has the distinguishing feature that the algorithm is run entirely by the computer and an external operator or technician cannot interfere with it. This is because the algorithm has a control system that checks against unnecessary tests right at the first stage of the invention. Applicant's invention is much needed and will make an impact on the cost of health care.

Applicant has made a diligent effort to place this application in condition for allowance and notice to the effect that claims 1-4, 21, 23, 24, 26 and 27 are in condition for allowance is earnestly solicited.

In addition, upon allowance of these generic claims, Applicant requests that claims 5-11, 13-20 and 25 be reinstated as being drawn to non-elected species, which was the condition of the Restriction Requirement.

Respectfully submitted,

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Date: April 5, 2004

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